

Remarks

Claims 2-9 and 16-26 are pending in this application. Claims 1 and 10-15 have been canceled without prejudice. Applicants reserve the right to file one or more continuing applications drawn to the subject matter of these canceled claims. Claims 2-4, 8, 9, and 16 have been amended to be dependent on claim 17. Claims 5 and 6 have been amended to incorporate subject matter from claims 13 and 15. Claim 18 has been amended to limit the scope of the macromolecular element of the claim. Applicants reserve the right to file one or more continuing applications drawn to the subject matter that was deleted from claim 18 as amended. Claims 20-26 are new and incorporate subject matter from claims 2-4, 8, 9, 13, and 16, respectively. No new matter has been added to the application by virtue of these amendments.

The application now contains five independent claims and 19 total claims. Applicants previously paid for six independent claims and 20 total claims. Therefore, no excess claims fees are required for these amendments.

I. Allowed and Allowable Subject Matter

Claim 19 was allowed. New claims 20-26 are dependent on claim 19. Therefore, claims 20-26 should be in condition for allowance.

Claims 13 and 15 were objected to as being dependent on a rejected base claim, but were deemed allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 13 and 15 have been canceled, but the subject matter thereof was incorporated into claims 5 and 6.

Claim 17 is written in independent form and contains all of the limitations of claim 13 and its base claim, there being no intervening claim. Thus, it is respectfully submitted that claim 17 and its dependent claims, i.e., claims 2-4, 8, 9, and 16, are in condition for allowance.

Therefore, claims 2-4, 8, 9, 16, 17, and 19-26 should be allowable.

II. Response to Objection on the Basis of Double Patenting

Claims 17 and 18 were objected to as allegedly being substantial duplicates of claims 13 and 14, respectively. Claims 13 and 14 have been canceled, thus the objection is moot.

Accordingly, withdrawal of the objection is respectfully requested.

III. Response to Rejections under 35 U.S.C. § 103(a)

A. Legal Foundation for Examination under 35 U.S.C. § 103(a)

Before responding directly to the issues raised by the Office Action under Section 103, the legal foundation for

sustaining such a rejection will be reviewed. Briefly, an applicant for a patent is entitled to the patent unless the application fails to meet the requirements established by law. 35 U.S.C. §§ 101, 102, 103, 112. It is the USPTO's duty to issue a patent or establish that the applicant is not entitled to a patent under the law. *In re Warner*, 154 USPQ 173, 177 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968). Thus, the initial burden is on the USPTO to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). If no *prima facie* case of obviousness is established, then a rejection under Section 103 cannot properly be sustained. *In re Oetiker*, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). If the USPTO establishes a *prima facie* case of obviousness, then the burden of production shifts to the applicant to provide appropriate rebuttal, although the burden of persuasion always remains with the USPTO. *Id.* Such rebuttal may include arguments, amendments, and/or presentation of objective indicia of nonobviousness. However, such objective indicia are always relevant to a determination of nonobviousness whether or not a *prima facie* case of obviousness has been established. *Stratoflex Inc. v. Aeroquip Corp.*, 218 U.S.P.Q. 871, 879 (Fed. Cir. 1987). To establish a *prima facie* case of obviousness, the USPTO must show all of the limitations of the claimed invention in the prior art. *In re Ehrreich*, 200 U.S.P.Q. 504, 509-11 (C.C.P.A. 1979). The subject matter of the invention must be

considered as a whole and through the eyes of a hypothetical person of ordinary skill, not expert skill, in the relevant art at the time the invention was made. *Connell v. Sears, Roebuck & Co.*, 220 U.S.P.Q. 193, 199 (Fed. Cir. 1983). References must also be considered as a whole, including subject matter that teaches away from the invention as well as subject matter that suggests the invention, and not for their isolated teachings. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 227 U.S.P.Q. 657, 669 (Fed. Cir. 1985). "[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. ____, 82 USPQ2d 1385, 1395 (2007) (citing *United States v. Adams*, 383 U.S. 39, 40, 148 USPQ 479 (1966)). Known elements may be combined if there would be a "reason for combining" them. *Id.*, 82 USPQ2d at 1397. That is, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art" because "inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id.* at 1396. In nonobviousness analysis, one must "guard against slipping into the use of hindsight" and "resist the temptation to read into the prior art the teachings of the invention in issue." *Graham*, 383 U.S. at 36, 148 USPQ at 474; *KSR*, 82 USPQ2d at 1397.

Finally, all the facts in evidence are evaluated, and patentability is determined on the totality of the record. *In re Corkill*, 226 USPQ 1005, 1008 (Fed. Cir. 1985). Factual determinations made by the USPTO must be based on a preponderance of the evidence, and legal conclusions must be correct. *In re Caveny*, 226 USPQ 1, 3 (Fed. Cir. 1985).

Pursuant to established legal authority, patentability under 35 U.S.C. § 103 requires a four-step factual analysis, which involves (1) determining the scope and content of the prior art, (2) ascertaining the differences between the prior art and the claimed inventions, (3) resolving the level of ordinary skill in the pertinent art, and (4) utilizing the objective evidence of nonobviousness that may have been presented. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). After all of these factors have been considered, the ultimate legal conclusion on the issue of obviousness must be reached. With the above background in mind the rejections under 35 U.S.C. § 103 will be discussed.

B. Factual and Legal Analysis

Claims 1-12, 14, 16, and 18 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,879,697 (Ding) in view of U.S. Patent No. 6,251,142 (Bernacca) and U.S. Patent No. 5,955,588 (Tsang). Claims 1, 10-12, and 14 have been canceled, thus the rejection as applied to these claims

is moot. As discussed above, claims 2-4, 8, 9, and 16 have been amended to be dependent on claim 17 and, thus, should be allowable. Therefore, the rejection will be discussed below in connection with claims 5-7 and 18.

Ding discloses drug-releasing coatings for medical devices.

The abstract states:

[T]he coating comprises at least two layers: an outer layer containing at least one drug-ionic surfactant complex overlying a reservoir layer containing a polymer and the drug which is substantially free of an ionic surfactant. Upon exposure to the body tissue of a medical device covered with such coating, the ionically bound drug in the outer layer is released into body fluid or tissue. Following release of such bound drug, the ionic surfactant binding sites in the outer layer are left vacant. To maintain the pharmacological activity after delivery of the ionically bound drug, additional amounts of the drug are embedded or incorporated in the reservoir layer in a manner which allows the drug, which is substantially free of ionic surfactants, to complex with the vacant binding sites of the ionic surfactant of the outer layer.

See also, column 2, line 62, to column 3, line 16. Ding further states:

The complexes formed according to the present invention will result primarily from ionic interactions between negatively charged drugs and positively charged surfactants or positively charged drugs and negatively charged surfactants. However, certain secondary forces may also exist to contribute to the formation or maintenance of the complexes, such as hydrogen bonding, dipole-dipole interaction, charge-dipole interaction

Column 4, lines 8-15. Thus, Ding discloses non-covalent bonds between a charged drug and an oppositely charged surfactant. Ding also discloses mixtures of the drug and a polymer. Column

4, lines 24-37. The drug and polymer are not bonded to each other, because bonding of the drug to the polymer would prevent the drug from being released, which is a property of Ding's invention. Column 3, lines 13-17. Therefore, Ding fails to disclose covalent bonds between heparin and anything.

Bernacca discloses an implantation device in which at least a portion of the surface of the device is coated with a receptor capable of binding selectively with a ligand formed by combining an active principle (i.e., a drug or a diagnostic; col. 4, lines 60-63) with a substance capable of binding specifically to the receptor. Col. 3, lines 1-6. Preferred receptors are disclosed at col. 3, lines 18-20. Binding pairs are disclosed at col. 4, lines 18-22. Biotinylated heparin is disclosed as an example of a ligand. Col. 6, lines 45-49. Thus, Bernacca discloses what is presumably a covalently bonded ligand, i.e., heparin covalently bonded to biotin (a receptor-binding molecule), and Bernacca discloses releasable, non-covalent bonding between the ligand and a receptor.

Tsang discloses an non-thrombogenic coating for blood-contacting surfaces of medical devices. The coating consists of heparin covalently bonded to a hydrophobic silyl moiety. The Office Action has interpreted the silyl moiety as disclosing a synthetic macromolecule bonded to a hydrophobic material.

1. Claims 5-7

Claims 5 and 6 have been amended to incorporate the subject matter of claims 13 and 15, which were deemed to be allowable if rewritten in independent form.

The combination of Ding, Bernacca, and Tsang fails to disclose or suggest each and every limitation of claims 5 and 6, as amended, and thus fails to render these claims unpatentable under Section 103. Dependent claim 7 incorporates by reference the limitations of its base claim, i.e., claim 6, and thus is free of the cited references, as well.

Therefore, withdrawal of the rejection of claims 5-7 over Ding, Bernacca, and Tsang is respectfully requested.

2. Claim 18

Claim 18 is equivalent to claim 14 rewritten in independent form, including all the limitations of its base claim and any intervening claims. Claim 14 was rejected based on the rationale that heparin is a polysaccharide, thus the same logic would apply to claim 18.

Although Applicants disagree that the combination of Ding, Bernacca, and Tsang discloses or suggests each and every element of claim 18, claim 18 has been amended by deleting the term "polysaccharides" to seek an early allowance of this application. Applicants respectfully submit that the combination of Ding, Bernacca, and Tsang fails to disclose or suggest each and every

limitation of claim 18, as amended, namely, wherein the macromolecule comprises a biopolymer of gelatin, collagen, alginate, hyaluronic acid, alginic acid, carrageenan, chondroitin, pectin, chitosan, and their derivatives and copolymers. Thus, the combination of cited references fails to render claim 18 unpatentable under Section 103. Accordingly, withdrawal of the rejection of claim 18 over Ding, Bernacca, and Tsang is respectfully requested.

IV. Summary and Conclusion

Should the Examiner deem it advisable to conduct a telephone interview for any reason, the undersigned attorney would be most agreeable to receiving a telephone call to expedite the prosecution of the application.

For the reasons given above, Applicants respectfully request reconsideration and allowance of Claims 2-9 and 16-26 and passage of this application to issue.

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Respectfully submitted,



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